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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,964

05/09/2007

Jeffrey D. Edwards

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

12/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,964	Applicant(s) EDWARDS, JEFFREY D.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/23/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the second Office Action based on the 10/595964 application filed May 9, 2007.

Claims 1-33 as amended are currently pending and considered below.

Response to Amendment

1. In light of the amendments to claim 14, the previous claim objection is hereby withdrawn.

Drawings

2. The drawings were received on September 23, 2009. These drawings are accepted.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,574,504 B1 to Mazaury et al.

Regarding the above claims, Mazaury et al teach an apparatus and method for facilitating transdermal delivery of a therapy comprising providing an electromagnetic field generating device (3, 7); a control device (5) to control the generating device to alternately produce active and substantially inactive electromagnetic field portions (Col. 4, lines 17-22), wherein the inactive electromagnetic field portion has no electromagnetic pulses (Col. 4, lines 17-19). Further, Mazaury et al teach that the electromagnetic field generating device is a coil, and the control device comprises a microcontroller (5) programmable by a user so that an electromagnetic signal corresponding to a substance delivery plan is produced which increases dermal permeability at one or more times for a specific period of time (Cols. 7-8). Mazaury et al further teach that the electromagnetic field generating and control device are embedded in a substantially flat member (3, 5; see Fig. 1), and that the therapeutic substance is a drug (the essential oils are used to provide treatment for various ailments, making them drugs).

Mazaury et al are silent, however, to the active electromagnetic field portions being shorter than the inactive electromagnetic field portions, as well as the active electromagnetic field portions having an electromagnetic field packet having a plurality of successive pulses. However, the process of varying the duration of electromagnetic delivery is taught by Mazaury et al and it therefore would have been obvious to one

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having ordinary skill in the art to experiment with various parameters of delivery, including pulse lengths and frequencies to determine the best combination to deliver a particular compound.

Mazaury et al are also silent the electromagnetic field generating device comprising a solid state switching device which can be a transistor. However, Mazaury et al describe the switching on and off of the electromagnetic field generating device, which indicates the need for a circuit component having the capability of activating or deactivating the coil, of which there are a limited number of options. Therefore, it would have been obvious to one having ordinary skill in the art to use a transistor as a solid state switching device in the electromagnetic field generating device in order to accurately control the activation and deactivation of the electromagnetic coil. Further, Mazaury et al do not explicitly teach that the waveforms being generally rectangular in configuration, as well as to the various ranges of energisation packet frequency, number of signal pulses, and duration of energy pulses. Regarding the shape of the waveform, any signal pulse having increasing and decreasing portions (ie: pulse on and pulse off), as well as a duration of the pulse, the waveform will be generally rectangular. Such is the case with Mazaury et al, and thus the above limitation is taught by Mazaury et al. Regarding the various ranges of frequency, number, and duration of the packets and pulses, Mazaury et al teach varying pulse intensity, duration, and frequency. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide electromagnetic pulses in the described ranges, since it has been held that where the general conditions of a

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claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding the limitation that the therapeutic substance is disposed on an outwardly facing surface of the apparatus, the examiner notes that Mazaury et al teach applying the essential oils to the scalp and then applying the electromagnetic energy. When the device is set atop the head, the examiner notes that the therapeutic substance will then be disposed on an outwardly facing surface of the apparatus.

Response to Arguments

6. Applicant's arguments filed September 23, 2009 have been fully considered but they are not persuasive.

7. In response to applicant's argument that the suggestion of the examiner to experiment with pulse lengths and frequencies is counter to the teachings of the prior art, the examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The examiner believes the device of Mazaury et al is no different in structure from the device of the instant claims, as applicant has indicated on page 8 of the arguments that Mazaury et al discloses an electromagnetic field generative device, a control device, and electromagnetic wave generator. The examiner observes simply that the intended

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use of Mazaury et al (to deliver essential oils to the scalp) is different than that of the applicant, and therefore it required different delivery parameters.

8. On page 9, paragraph 4, applicant appears to be presenting an argument that the results produced by their device are unexpected within the art, however applicant appears to provide no evidence aside from conclusory statements as the basis for this argument. The evidence relied upon should establish “that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance.” *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). MPEP 706.02(b). The examiner further notes that experimentation as defined by the examiner always delivers the predictable and expected result of the control device controlling the field generating device to produce active and inactive electromagnetic field portions, regardless of their effect on any topical treatment applied to the patient.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763